



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-391]

Controlled Substances: 2014 Proposed Aggregate Production Quota for 10 Temporarily Controlled Synthetic Cathinones

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of a proposed 2014 aggregate production quota for ten synthetic cathinones.

SUMMARY: Ten synthetic cathinones: 4-methyl-*N*-ethylcathinone (4-MEC); 4-methyl- α -pyrrolidinopropiophenone (4-MePPP); α -pyrrolidinopentiophenone (α -PVP); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone); 2-(methylamino)-1-phenylpentan-1-one (pentedrone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone); 4-fluoro-*N*-methylcathinone (4-FMC); 3-fluoro-*N*-methylcathinone (3-FMC); naphthylpyrovalerone (naphyrone); and α -pyrrolidinobutiophenone (α -PBP) were temporarily placed in schedule I of the Controlled Substances Act (CSA) by a final order published by the Drug Enforcement Administration (DEA) on March 7, 2014 (79 FR 12938). This means that any manufacturer that wishes to manufacture 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α -PBP after March 7, 2014, must be registered with the DEA and have obtained a manufacturing quota for 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α -PBP pursuant to 21 CFR part 1303.

The DEA cannot issue individual manufacturing quotas for 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or α -PBP unless and until it establishes an aggregate production quota. Therefore, this notice proposes a 2014 aggregate

production quota for 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α -PBP.

DATES: Comments or objections should be received on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-391” on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at www.regulations.gov for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Written comments submitted via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

The Freedom of Information Act applies to all comments received. All comments received are considered part of the public record and made available for public inspection online at www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file.

If you wish to inspect the DEA's public docket file in person by appointment, please see the For Further Information Contact paragraph.

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA) by 28 CFR 0.100. The

Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The DEA established the 2014 aggregate production quotas for substances in schedules I and II on September 9, 2013 (78 FR 55099). Subsequently, on January 28, 2014, the DEA published in the Federal Register a notice of intent to temporarily place ten synthetic cathinones: 4-methyl-*N*-ethylcathinone (4-MEC), 4-methyl- α -pyrrolidinopropiophenone (4-MePPP), α -pyrrolidinopentiophenone (α -PVP), 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 2-(methylamino)-1-phenylpentan-1-one (pentedrone), 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 4-fluoro-*N*-methylcathinone (4-FMC), 3-fluoro-*N*-methylcathinone (3-FMC), naphthylpyrovalerone (naphyrone), and α -pyrrolidinobutiophenone (α -PBP) in schedule I of the CSA (79 FR 4429). On March 7, 2014, the DEA published in the Federal Register a final order to temporarily place these ten synthetic cathinones in schedule I of the CSA (79 FR 12938), making all regulations pertaining to schedule I controlled substances applicable to the manufacture of these ten synthetic cathinones, including the requirement to obtain a manufacturing quota pursuant to 21 CFR part 1303.

4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α -PBP were non-controlled substances when the aggregate production quotas for schedule I and II substances were established, therefore, no aggregate production quotas for 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α -PBP were established at that time.

In determining the 2014 aggregate production quotas of these ten synthetic cathinones, the Deputy Administrator considered the following factors in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11: (1) Total estimated net disposal of each substance by all manufacturers; (2) estimated trends in the national rate of net disposal;

(3) total estimated inventories of the basic class and of all substances manufactured from the class; (4) projected demand for each class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Deputy Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Deputy Administrator, therefore, proposes that the year 2014 aggregate production quotas for the following temporarily controlled schedule I controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Proposed 2014 Quota
1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15 g
1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15 g
2-(methylamino)-1-phenylpentan-1-one (pentedrone)	15 g
3-fluoro-N-methylcathinone (3-FMC)	15 g
4-fluoro-N-methylcathinone (4-FMC)	15 g
4-methyl-N-ethylcathinone (4-MEC)	15 g
4-methyl- α -pyrrolidinopropiophenone (4-MePPP)	15 g
α -pyrrolidinobutiophenone (α -PBP)	15 g
α -pyrrolidinopentiophenone (α -PVP)	15 g
naphthylpyrovalerone (naphyrone)	15 g

Comments

Pursuant to 21 CFR 1303.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Deputy Administrator may hold a public hearing on one or more issues raised. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Deputy Administrator will publish in the Federal Register a final order

establishing the 2014 aggregate production quota for 4-MEC, 4-MePPP, α -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and α -PBP.

Dated: March 24, 2014

Thomas M. Harrigan,
Deputy Administrator.

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